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·				2142	

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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
Office Action Commons	09/765,218	HALLER ET AL.				
Oπice Action Summary	Examiner	Art Unit				
	Prieto B.	2142				
10) ☐ The drawing(s) filed on 18 January 2001 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau * See the attached detailed Office action for a list of	s have been received. s have been received in Applicati ity documents have been receive ı (PCT Rule 17.2(a)).	ion No ed in this National Stage				
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date U.S. Patent and Trademark Office PTOL-326 (Rev. 7-05) Office Ac	6) Other:					

DETAILED ACTION

1. This communication is in response to Amendment filed 11/01/05, claims 1 and 16 have been amended, and claims 1-29 and 31-33 remain pending.

Claim Objection

- 2. Claim 1 recites the limitation "the mobile phone" and "the remote computer center" in (f) limitation. There is insufficient antecedent basis for this limitation in the claim. For the purposes of examination, this has been taken as the mobile telephone and the remote computer system, respectively, previously mentioned. Applicant is urged to review other claim(s) amendment for similar deficiency.
- Claim 32 is allowed.

Claim Rejection

- 4. Quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action may be found in previous office action.
- 5. Claims 1-11, and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snell in view of Nappholz in further exemplified by Akiyama et. al. (US 5,386,468)

Regarding claim 1, Snell teaches features of the claimed invention, teachings the system/method of Figs. 1-4, comprising:

an implantable medical device (IMD) (16) implanted with the body of a patient (col 4/lines 10-15);

the IMD being capable of bi-directional communication with a communication module (col 1/line 55-col 2/line 9 and col 2/lines 34-42), the communication module (10) located outside/external to the patient's body (col 7/lines 16-25, 43-56), adapted to establish a communication with the IMD via a communication protocol (7/lines 43-59) including a wireless link (col 9/lines 45-55);

the communication module configured to establish a bi-directional communication with the IMD (col 1/line 55-col 2/line 9 and col 2/lines 40-42);

- a remote communication system (12 of Fig. 1);
- a wireless communication system adapted to establish a bi-directional communication

with the remote computer system (col 5/lines 2-36, 51-65) over a wireless communication medium (col 9/lines 45-55); however Snell is silent regarding the use of a mobile telephone;

Nappholz teaches a system/method related to medical devices, including a cellular telephone (14 of Fig. 5) (col 2/line 66-col 3/line 9, col 5/lines 20-25) communicatively coupled to a communication module and configured to send and receive information (col 2/lines 46-52 and col 4/lines 6-25) and further communicate with a remote computer system (27) (col 4/lines 6-25) via cellular telephone and a communication system (26) (col 4/lines 6-11) over a wireless communication link (col 4/lines 6-25);

a communication cellular system (26) adapted for establishing bi-directional communication with the mobile telephone (14) and the remote computer system (27) (col 2/lines 66-col 3/line 20, col 4/lines 6-25) and the mobile phone and the IMD (col 2/lines 66-col 3/line 20, over a cellular telephone network col 13/line 47-56-col 14/line 30); a communication cellular system (26) adapted for establishing a bi-directional communication between other mobile telephones ("pair of mobile telephones") holding private conversations (col 4/lines 6-25);

communication module (14) comprising a mobile telephone for establishing a bi-directional (link of Fig. 1) communication with the IMD (col 4/lines 6-9) and establish communication bi-directional with the remote computer system (27) (col 4/lines 6-25);

wherein the communication module has means for storing over time-collected patient related information "mining patient history" (col 7/lines 8-19, col 8/lines 19-28, 44-48 and col 15/lines 60-65); although Snell and Nappholz teach a mobile phone configured to relay data from the IMD to the remote computer system and from the remote computer system to the IMD, they are silent with respect to generating a charge, tally, bill or statement (i.e. "invoice") when this communication is initiated.

Akiyama discusses as prior art that when a personal communication terminal such as a portable (mobile) telephone initiates a data communication, via radio link provided by a carrier (communications service carrier), the mobile telephone first transmits its identification number, and the carrier identifies the transmitted identification number as legitimate or illegitimate; if it is identified as legitimate, the communication requested is allowed to take place, at which time the carrier initiates a billing procedure to charge the user corresponding to the identification number (col 1/lines 5-31).

It would have been obvious to one of ordinary skill in the art at the time the invention was made given the teachings of Snell and Nappholz teaching a communication module/mobile telephone relaying data from the IMD to the remote computer system and from the remote computer system to the IMD, the billing of invoice procedure discussed by Akiyama as prior art related to a mobile telephone establishing a data communication provided by a service carrier, e.g. to remote computer system and to the IMD, would have been inherent. Further given the suggestions of Nappholz for including the transmission of data

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obtained from the monitored device over a cellular network using a mobile telephone, the discussion of Akiyama regarding the billing procedure associated with a mobile phone would have been readily apparent. At the time the invention was made a mobile telephone upon initiating a data communication via radio link provided by a carrier (communications service carrier), the carrier at this time would have initiates generated a charge to the user. One of ordinary skill in the art at the time the invention was made would have been motivated apply security measure to prevent unauthorized use of the identification number, as noted by Akiyama as an present deficiency of the prior art.

Regarding claim 2, invoice generation means are incorporated into the communication system, for example communicatively connectable to the medical device for receiving information therein (Kroll: col 3/lines 21-43).

Regarding claim 3, invoice generation means are incorporated into a telephone system included in the communication system (Kroll: col 7/lines 5-16).

Regarding claim 4, system of claim 1, further comprising means for electronically transmitting generated invoices to at least one predetermined location for further processing and billing (Kroll: col 4/lines 7-14).

Regarding claim 5, means (12 of Fig. 1) for calculating the amount of each invoice in accordance with the number, type or frequency of services provided to the patient by the system (Kroll: col 3/line 53-col 4/line 2).

Regarding claim 6, means (12 of Fig. 1) for calculating the amount of each invoice in accordance with the type or identification indicia stored in communication module or IMD (Kroll: col 3/line 53-col 4/line 2).

Regarding claim 7, wherein the remote computer system further comprises means for making a remote diagnostic assessment of the patient's condition on the basis of the information relayed thereto by the IMD or the communication module (Nappholz: col 13/line 47-col 14/line 36).

Regarding claim 8, although Kroll teaches generating an invoice on the basis of the information relayed by the IMD, it does not teach invoice generation in response to a diagnostic assessment;

Official Notice (see MPEP § 2144.03 Reliance on "Well Known" Prior Art) is taken that health care providers and services including health management organization that provide means for

quantitatively analyze said providers and services was old and well known in the art. For example and not limited to, the Dang reference (US 5,835,897) discussed as prior art, a medical reimbursement computer system including means (computer implementation) of estimating health care services/consumption through the use of diagnostic and patient's illness data relationships and computing or calculating the amount of payment to the health provider. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to include means for generating an invoice based on a statistical diagnostic assessment which minimizes variances, motivation would be to automatically further determine an expected cost of treatment based on obtained diagnostic.

Regarding claim 9, wherein the remote computer system further comprises means for remotely executing a remedial response or therapy on the basis of the information relayed thereto by at least one of the IMD and the communication module (col 13/line 47-col 14/line 36.)

Regarding claim 10, this claim is substantially the same as claim 8, thereby same rationale of rejection is applicable.

Regarding claim 11, wherein the communication module is incorporated into the mobile telephone (Nappholz: 14 of Figs. 3-4, col 3/lines 1-65 and col 5/lines 20-25).

Regarding claim 13, wherein the IMD and the communication module communicate with one another using radio-frequency telemetry (Nappholz: col 4/lines 6-9, Fig. 2 and col 5/lines 15-19 also Snell: see 14 of Fig. 1).

Regarding claim 14, wherein the means for generating an invoice is incorporated into a wireless network (Nappholz: col 7/lines 23-27).

Regarding claim 15, generating automatic invoices in response to a patient-initiated (Kroll: col 4/lines 31-63).

6. Claims 16-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snell-Nappholz in view of Akiyama et. al. in further view of Imran (US 4,705,043).

Regarding claim 16, this claim is substantially the same as the combined claims 1, and 11, thereby, same rationale of rejection is applicable. The mobile telephone or the PDA send and receive simultaneously information to and from the IMD over a communication system (Nappholz: bidirectional communication between telephone/PDA and IMD col 13/line 47-56-col 14/line 30); however the above-mentioned prior art does not teach where the bi-directional communication is simultaneously.

Imran discusses an IMD (1) adapted to communicate with a communication module (2), wherein the IMD is adapted to establish a bi-directional communication with the communication module (col 2/lines 14-20) over a wireless communication system (col 3/lines 34-40), where the bi-directional communication occurs simultaneously in real time (col 1/lines 5-16, col 2/lines 63-col 3/lines 2).

It would have been obvious at the time the invention was made to given the suggestion of Snell for monitoring an implantable medical device on a patient including the use of wireless communication mediums, the teachings of Imran for doing the same would be readily apparent. One would be motivated to incorporate Imran's teachings for establishing a two-way communication link over a wireless communication system among other as suggested and for receiving and transmitting in real-time simultaneously, avoiding the use of wires extending through the patient's skin for monitoring and conducting electrophysiology studies without further surgical implant.

Regarding claims 17-29, these claims are substantially the same as claims 2-13, 14-15, respectively, same rationale of rejection is applicable.

Claim 30 (canceled)

7. Claims 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snell-Nappholz in view of Kroll et. al. in further view of Stutman et. al. (US 5,576,952).

Regarding claim 31, this claim is substantially the same as the combined claims 1, 11 and 16, thereby, same rationale of rejection is applicable. The mobile telephone or the PDA send and receive simultaneously information to and from the IMD over a communication system (Nappholz: bidirectional communication between telephone/PDA and IMD col 13/line 47-56-col 14/line 30); however the above-mentioned prior art does not teach where the bi-directional communication is simultaneously broadcasted, i.e. broadcasting an alert to multiple computers: "remote health care provider", a "remote" computer, and a "remote expert-based" computer system.

Stutman discloses a medical alert distribution system (Fig. 1, 10) for distributing medical information from ambulatory patients (col 4/lines 32-42) to health care providers "subscribers" (col 1/lines 34-45) over a wireless communication network (col 5/lines 20-39), subscriber units may include computers (col 3/lines 20-37, col 4/lines 8-16), distribution comprises broadcasting during a given period to a group of predetermined subscribers (col 8/lines 56-col 9/lines 13).

It would have been obvious to one ordinary skilled in the art at the time the invention was made given the suggestions of Snell for monitoring an implantable medical device on a patient including the use of wireless communication mediums, the teachings on Stutman for the same purpose further including the transmission of data obtained from the monitored device over a cellular network, would be readily apparent. One would be motivate to broadcast to multiple different processing devices including computer terminals, portable computers and pagers data from telemetry devices not limited to the one suggested by Stutman, where an independent processes allow efficient operation of the alert distribution system because the processes may perform their function in parallel within the host distributor computer or on separate machines having additional resources.

8. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over NOLAN et. al. U.S. Patent No. 5,404,877 (Nolan hereafter) in view of Kroll in further view of Snell in further view of Stutman et. al. (US 5,576,952).

Regarding claim 33, Nolan teaches substantial features of the invention, including a system (of Fig. 12) further including: an implantable medical device (5) (col 3/lines 28-36); a remote computer system (220 or 260);

the implantable medical device capable of sending/receiving communication with a communication module (240) located external to the patient's body to a remote communication system (220/260) (col 23/lines 65-68 and col 24/lines 14-20);

- a cellular/telephonic communicator (240) capable of exchanging information with the communication module (col 23/lines 49-67 and col 24/lines 14-20);
- a communication system (Fig. 12) supporting bi-directional communication with the cellular/telephonic communicator (240) external to the patient's body and the remote computer system (260 or 220) (medical device sending to all, i.e. communicator 240 and remote computers (260 & 220) see col 23/lines 65-68 and sending from computer system to medical device see col 24/lines 14-20); further including a method comprising:

the implantable medical device configured to determine that medical attention should be provided to the patient and provide a warning signal based on said determination (col 2/lines 44-56, col 5/lines 56-60, col 6/lines 60-67, and col 9/lines 10-22, 26-31);

in response to determining that medical attention should be provided sending data from the implantable medical device to the communication module (col 6/lines 60-67, col 9/lines 16-19) for an external remote computer system device;

remotely analyzing the data (col 24/lines 23-26);

determining on the basis of the analyzed data whether remedial action respecting the IMD is required (col 24/line 26-30);

remotely executing the determined remedial action via the communication system which supports communication to the IMD or patient therein (col 24/lines 33-38), however Nolan is silent with regards to invoice generation means in his system, and further the claimed functions performed by the communication module and those performed by the mobile telephone are performed by one element, (i.e. 240) in the Nolan reference;

Kroll teaches a system/method related to generating invoice entity usable with medical devices, specifically, an communication device (12 of Fig. 1) comprising invoice generating entity communicatively couple to a medical device (21 of Fig. 1) (col 3/lines 21-49), the invoice generating device configured to generate an invoice (col 3/lines 62-col 4/line 14, col 5/lines 8-15, 43-68), when communication between the medical device is initiated the communication device invoicing entity (col 4/lines 41-63), however Nolan not Kroll teach detecting a remote computer

Snell teaches wherein the communications system is adapted to detect the remote computer system e.g. by means of a transmission protocol involving handshaking (Snell: col 7/lines 43-59).

It would have been obvious to one ordinary skilled in the art at the time the invention was made given the suggestions of Nolan of a telephonic communicator external to the patient's body, specifically, communicatively coupled to the IMD for sending/sending data thereto, also having mobile phone capabilities for receiving data from the IMD and establishing a telephonic communication with programmable telephone numbers thereby sending messages over a cellular telephone link to remote computer systems. Nolan teaches that these components although not shown individually (microprocessor and sending/receiving circuitry) are also present in the elements 220 and 230. It would be readily apparent to one ordinary skilled in the art that these component are relocatable being either integrated or distributed, e.g. the separation of the telephonic functionalities and the bi-direction communication circuitry would enable multiple patients at home complex building facility each having telephonic functionality components communicate remotely with their individual health car provider's office via one

bi-directional communication circuitry. Furthermore, it would have been obvious to one ordinary skilled in the art at the time the invention was made given the suggestions of Nolan for monitoring an implantable medical device on a patient, the teachings of Snell for doing the same, would be readily apparent and the teachings on Kroll for providing monetary reimbursement for medical services provided, including invoice generation mechanism would be readily apparent, one would be motivated given the mechanism's transmission, self-contained modularity and add-on capability of Kroll's device, further including the transmission of the formatted invoice and the reception of data from a remote location over a model, to generate invoices in the primary reference's system for transmission to remote locations to base remuneration of services provided based on the actual metered usage of the medical device of the patient.

However, the above-mentioned prior art does not teach where the bi-directional communication is simultaneously broadcasted, i.e. broadcasting an alert to multiple computers: "remote health care provider", a "remote" computer, and a "remote expert-based" computer system.

Stutman discloses a medical alert distribution system (Fig. 1, 10) for distributing medical information from ambulatory patients (col 4/lines 32-42) to health care providers "subscribers" (col 1/lines 34-45) over a wireless communication network (col 5/lines 20-39), subscriber units may include computers (col 3/lines 20-37, col 4/lines 8-16), distribution comprises broadcasting during a given period to a group of predetermined subscribers (col 8/lines 56-col 9/lines 13).

It would have been obvious to one ordinary skilled in the art at the time the invention was made given the suggestions of Nolan for monitoring an implantable medical device on a patient including the use of wireless communication mediums, the teachings on Stutman for the same purpose further including the transmission of data obtained from the monitored device over a cellular network, would be readily apparent. One would be motivate to broadcast to multiple different processing devices including computer terminals, portable computers and pagers data from telemetry devices not limited to the one suggested by Stutman, where an independent processes allow efficient operation of the alert distribution system because the processes may perform their function in parallel within the host distributor computer or on separate machines having additional resources.

9. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Snell-Nappholz in view of Kroll Akiyama et. al. in further view of OTSUKA, Ideal state of high density packing view from wiring technology from human brain to LSI and electronic packaging on circuit boards.

Regarding claim 12, however the above-mentioned references do not teach a mobile telephone comprising a PDA.

Otsuka teachings the integration of separate electronic communication components, such as a mobile telephone and a PDA. It would have been obvious to one ordinary skilled in the art at the time the invention was made to further integrate separate application, e.g. PDA to the Nappholz system presently integrating the functionalities of a programmable device and a personal computer application configured for receiving/transmitting telemetry data, with cellular telephone technology, for taking the applied reference teaching a step further, using the advantages of LSI technology and further incorporate a PDA, the size of a card, motivation would be to further provide the patient a more user friendly/portable device that existing prior arts as suggested by the Nappholz reference.

Response to arguments

10. Regarding claims 1-11 and 13-15 rejected under 103 as being unpatentable over Snell in view of Nappholz in further view of Kroll, it is argued Kroll does not teach monitoring for the purpose of communicating information between a patient's IMD and a central monitoring station.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). It is further noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

11. Regarding claims 1-11 and 13-15 rejected under 103 as being unpatentable over Snell in view of Nappholz in further view of Kroll, it is argued that the applied prior art does not teach invoicing in response to a communication initiated when the mobile phone relays data from the IMD to the remote computer system and when the mobile phone relays data from the remote computer system to the IMD.

In response to the above-mentioned argument, applicant's interpretation of the applied prior art has been considered. However, according to the discussion of prior art exemplified by Akiyama, this is inherent in the Nappholz system utilizing a wireless/cellular phone communicating via a radio based

communication medium. Specifically, it was old and well known given the disclosure in the Akiyama patent that a mobile telephone initiates a data communication via radio link provided by a carrier (communications service carrier), the personal communication terminal first transmits its identification number, if it is identified as legitimate by the carrier, the communication requested is allowed to take place (data communication, i.e. "relay data"), at which time the carrier initiates a billing procedure to charge the user corresponding to the identification number. It would have been obvious at the time of the invention charging the user of the mobile phone in response to a communication initiating when the mobile phone relays data from the remote computer system to the IMD and from the IMD to the remote computer system.

12. Regarding claims 16-29 rejected under 103 as being unpatentable over Snell-Nappholz in view of Kroll in further view of Imran, it is argued that there is no motivation to provide the Snell-Nappholz with invoicing capabilities.

In response to the above-mentioned argument, however Nappholz teaching of using a cellular phone supported by a standard cellular network is to provide a system, which allows full mobility to the patient and utilizes an existing commercially available communication i.e., telephone network to enable the patient and/or the device to communicate at will with a physician, hospital or other health care facility. Given that the system is supported by a commercially available network system it is obvious that the accurate recordation of call activity is dependent on the ability of the cellular mobile telephone provider to uniquely identify each mobile subscriber unit operating within the service area as a billable entity by the carrier, noted by Akiyama, e.g. to prevent lost revenues or the theft of services.

13. Regarding claim 12 rejected under 103 as being unpatentable over Snell-Nappholz in view of Kroll and further in view of Otsuka, it is argued that because of its dependency to claim 1, this claim too can be viewed as covering patentable subject matter.

In response to the above-mentioned argument, claim 1 has been rejected as failing to cover patentable subject matter, thereby, claim 12 dependent from independent claim 1, based on the argued rationale fails to cover patentable subject matter. Further, it is respectfully noted that applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claim (12) patentably distinguishes them from the references.

14. Regarding claims 31 and 33 rejected under 103 as being unpatentable over Snell-Nappholz in view of Kroll and in further view of Stutman et. al. it is argued that the same rationale related to claims 1 and 16 are applicable.

In response to the above-mentioned argument, claim 1 and 16 have been rejected as failing to cover patentable subject matter, thereby, claim 31 based on the argued rationale fails to cover patentable subject matter. Further, it is respectfully noted that applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claim (31) patentably distinguishes them from the references. The motivation to provide the Snell-Nappholz with Kroll was presented on page 3 of office action mailed 8/01/05.

- 15. Applicant's arguments filed 11/01/05 have been fully considered but not rendered persuasive.
- 16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prieto, B. whose telephone number is (571) 272-3902. The Examiner can normally be reached on Monday-Friday from 6:00 to 3:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's Supervisor, Andrew T. Caldwell can be reached at (571) 272-3868. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3800/4700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system, status information for published application may be obtained from either Private or Public PAIR, for unpublished application Private PAIR only (see http://pair-direct.uspto.gov or the Electronic Business Center at 866-217-9197 (toll-free).

Any response to this action should be mailed to:

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PRIMARY EXAMINER

B. Prieto Primary Examiner TC 2100 December 13, 2005